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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Andrew Thomas Forsberg

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HOLLAND & HART LLP

60 E. South Temple, Suite 2000

P.O. Box 11583

Salt Lake City, UT 84110

EXAMINER

OU, JING RUI

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/688,365	Applicant(s) FORSBERG, ANDREW THOMAS	
	Examiner JING OU	Art Unit 3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is responsible to the amendment filed on 11/07/2008. Claims 1-62 are pending. Claims 1, 21, 33, 38, 43, 50, 55, and 60 are independent.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-62 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The recitation "wedge shaped" in Claims 1, 21, 33, 38, 43, 50, 55, and 60 does not have sufficient support in the original disclosure and is considered as new matter. The term "wedge" at least can be defined as either "any shape that is triangular in cross section" or "a polyhedral solid defined by two triangles and three trapezoid faces."

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-41, 43-48, 55, 60, and 61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US Pat. No.: 5,681,334) in view of Nash et al (US Pat. No.: 5,662,681) and Goble et al (US Pat. No.: 5,702,397).

In regard to Claims 1-41, 43-48, 55, 60, and 61, Evans et al discloses a vascular closure assembly, comprising: a collagen (**22**); a suture (**24A, 24B, and 24C**) extending through the collagen; a housing (**46**); a tamping tube (**28**); a straight channel (**48**); a suture locking mechanism (movement of inner surface of 48, Col. 8, lines 40-57) residing in the housing; wherein the vascular closure mechanism comprises a non-locked position (the non-locking position occurs when 48 is not collapsed, Col. 8, lines 40-57) and a locked position (the non-locking position occurs when 48 is collapsed, Col. 8, lines 40-57); wherein the suture would engage the suture locking mechanism; wherein the locking mechanism has at least one locking element (inner surface of 48), wherein the at least one locking element has a first orientation (the first orientation occurs when 48 is not collapsed, Col. 8, lines 40-57) and a second orientation (the second orientation occurs when 48 is collapsed, Col. 8, lines 40-57); the first orientation providing the suture with a relatively non-tortuous path; the second orientation providing

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the suture relative tortuous path (Fig. 14 and Col. 8, lines 40-57); the tortuous suture pathway is formed by narrowing of the channel (Fig. 14 and Col. 8, lines 40-57); wherein the housing includes a distal open end.

Evans et al does not appear to disclose an anchor, the channel comprises at least one curved portion, and the claimed structure of the suture locking assembly or the claimed suture locking mechanism. Evens et al also does not appear to disclose that the suture locking mechanism including a wedge shaped portion.

However, Nash et al teaches a vascular closure assembly, comprising: an anchor (**32**). Evans et al and Nash et al are analogous art because they are from the same field of endeavor. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Evans et al and Nash et al before him or her, to modify the vascular closure assembly of Evans et al to include an anchor as taught by Nash. The suggestion/motivation for doing so would have been to maintain the vascular closure assembly to be secured to the vascular aperture (Nash et al, Fig. 3). Applicant should be noted that the curved portion of the channel is only a design choice and within the skill of one of ordinary skill in the art.

Furthermore, Goble et al teaches a system comprising: a housing (**101**), a channel (**103**); and a suture locking mechanism including a wedge shaped portion (wedge shaped gear unit of **107**, Fig. 13); wherein the locking mechanism changes from the non-locking position to the locking position by sliding movement (Fig. 13, slide movement of suture and cylinder 107 along the channel); wherein the wedge shaped portion of the locking mechanism is spaced apart from the housing (Fig. 18); wherein

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wedge shaped portion of the locking mechanism is in engagement with the housing (Fig. 18); wherein the wedge shaped portion of the locking mechanism includes a planar surface (the planar surface of each wedge shaped gear unit); wherein the suture locking mechanism comprises at least one channel (**103**) through the housing; wherein the at least one channel is arranged such that it provides a substantially non-tortuous suture path when the suture locking mechanism is in the non-locking position; and the at least one channel is arranged such that it provides a substantially tortuous suture path when the suture locking mechanism is in the locked position (Fig. 18); wherein the non-tortuous path is substantially parallel to the suture and the tortuous path has at least a portion that is substantially non-parallel to the suture (Fig. 18); wherein the channel is substantially straight (Fig. 18); wherein the channel has at least one bend (the channel 103 has a curved wall, Fig. 18); wherein the locking mechanism is triangular shaped (the wedge shape gear unit of 107 is triangular shaped); wherein the locking member includes at least three exterior surfaces (surface areas of gear units and wall of the housing); wherein the locking mechanism includes at least one exterior surface arranged for engagement by the suture; wherein the suture locking mechanism comprises at least one pair of mating surface (Fig. 18); wherein the channel comprises: a wide end (**109**); a narrow end (**105**); and at least one curve; wherein the narrow end comprises a notched surface (Fig. 18);

Applicant should be noted that it is only a design choice and within one of ordinary skill in the art to modify the vascular closure assembly of Evan et al. to include the suture locking mechanism as taught by Goble et al. It would have been obvious to

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have applied any of the various suture locking mechanisms or device as taught by Goble et al instead of that disclosed by Evans, as merely an obvious alternative suture locking mechanism or device capable of performing the same task in the same manner as Evans's. Applicant should be noted that it is only a design choice to make the wedge shaped portion includes either an acute angled portion or an obtuse angled portion. In addition, the cause of the sliding movement is only a design choice as long as the locking mechanism properly locks the suture by rotating the non-locked position to the locked position.

Therefore, it would have been obvious to combine Nash et al and Goble et al with Evans et al to obtained the invention as specified in the instant claims.

7. Claims 42, 49-52, 54, 56-59, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US Pat. No.: 5,681,334) in view of Nash et al (US Pat. No.: 5,662,681) and Goble et al (US Pat. No.: 5,702,397) and further in view of Schwartz et al (US Pat. No.: 6,293,961).

In regard to Claims 42, 49-52, 54, 56-59, and 62, Evans et al in view of Nash et al and Goble et al discloses all the limitations of the claims except claimed structures of the housing which serves as part of locking mechanism.

However, Schwartz et al teaches a vascular closure assembly, comprising: a housing (**60**), the housing comprises at least a first hole (the conical hole of 60, Fig. 7) corresponding to the first position and at least a second hole (the cylindrical hole of 60) corresponding to the second position; and a locking device or inner housing assembly (**20**), the locking device or inner housing assembly comprises at least a tab (**34**);

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wherein the housing comprises sidewalls (Fig. 7), such that sidewalls provide angle inwards from at least the first hole to at least the second hole; wherein the inward slope of the sidewalls provides a compressive force on the locking device tending to cause the plurality of mating surfaces to move toward each other; wherein the locking device is made of a bio-resorbable material (Col. 2, lines 24-31).

Applicant should be noted that it is only a design choice and within one of ordinary skill in the art to modify the vascular closure assembly of Evan et al in view of Nash et al and Goble et al to include the suture locking mechanism as taught by Goble et al. It would have been obvious to have applied any of the various suture locking mechanisms or device as taught by Goble et al instead of that disclosed by Evans in view of Nash et al and Goble et al, as merely an obvious alternative suture locking mechanism or device capable of performing the same task in the same manner as Evans's in view of Nash et al and Goble et al. The motivation/suggestion for having the locking device to be made of a bio-resorbable material would have been to have the body to degrade the material without performing another surgery to remove the device.

8. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over Evans et al (US Pat. No.: 5,681,334) in view of Nash et al (US Pat. No.: 5,662,681), Goble et al (US Pat. No.: 5,702,397) and Schwartz et al (US Pat. No.: 6,293,961), as applied to claim 50 above, and further in view of Bonutti et al (US Pat. No.: 6,159,234).

In regard to Claim 53, Evans et al in view of Nash et al, Goble et al, and Schwartz et al discloses all the limitations of the claims but fails to disclose that the expansion of the collagen provides a force that tends to seat the at least one mating

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surface and the at least one lower surface. However, Bonutti et al discloses a suture locking mechanism that locks a suture by a force that tends to seat the at least one mating surface and the at least one lower surface (Fig. 20). By modifying vascular closure assembly of Evans et al in view of Nash et al, Goble et al, and Schwartz et al to include the suture locking mechanism of Bonutti et al, the collagen of Evan et al would be able to provide a force that tends to seat the at least one mating surface and the at least one lower surface. Applicant should be noted that it is only a design choice and within one of ordinary skill in the art to modify the vascular closure assembly of Evan et al in view of Nash et al, Goble et al, and Schwartz et al to include the suture locking mechanism as taught by Bonutti et al. It would have been obvious to have applied any of the various suture locking mechanisms or device as taught by Bonutti et al instead of that disclosed by Evans, as merely an obvious alternative suture locking mechanism or device capable of performing the same task in the same manner as Evans's.

Response to Arguments

9. Applicant's arguments filed on 11/07/2008 have been fully considered but they are not persuasive. The allegation on page 24-27 of the remarks that Goble does not teach a locking device having wedge shaped portion is incorrect. The cylinder 107 Goble clear shows wedge shaped portion (the gear unit on the outer surface of 107) having triangular cross-sectional area (Fig. 18).

Conclusion

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JING OU whose telephone number is (571)270-5036. The examiner can normally be reached on M-F 7:30am - 5:00pm, Alternative Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Uyen (Jackie) T Ho can be reached on (571)272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JO

/(Jackie) Tan-Uyen T. Ho/

Supervisory Patent Examiner, Art Unit 3773